

REMARKS

Claims 1-12 and 19-22 are pending in this case. Claims 13-18 and 23-25 are canceled without prejudice or disclaimer. In its Decision on Appeal, the Board of Appeals vacated the rejection of Claims 1-12 and 19-22 for obviousness and entered a new ground of rejection under 37 CFR 1.196(b), the rejection being under 35 U.S.C. § 112, second paragraph, for indefiniteness. Consequently, this amendment is appropriate for consideration under 37 CFR § 1.196(b)(1).

Claim 7 was amended to substitute the word saliva for salvia to correct a typographical error.

Claims 1, 7 and 19 have been amended to clarify that the claimed chewing gum includes less than a typical amount of medicament to achieve a bioequivalent effect.

Support for the amendment can be found in the specification at Page 6, lines 12-14 and Page 7, line 27-32 which discloses that lower amounts of medicaments and agents than is typical can be administered while achieving the same effect or bioequivalence.

As apparent from the specification the invention is intended to apply to a wide range of drugs and agents (Page 8, lines 22-33) and one of skill in the art would understand that absolute amounts of the active agents in gum would vary depending upon the agent. While exemplary amounts have been provided in the specification in certain instances, for example at page 9 at lines 1-25; as indicated at Page 9, lines 26-31, exact dosing regimens will depend on the agent or medicament. One of skill in the art would understand that for FDA approved drugs, typical amounts would be the approved amounts and the amount used in a gum formulation would clearly be the amount that delivers the bioequivalent of an approved dosage. Where different dosages are approved and used, various gum compositions would deliver bioequivalent amounts for the different approved dosages. For other agents, typical amounts can easily be identified by one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography. The specific amount of an agent incorporated into a gum for delivering a bioequivalent amount can be determined by one skilled in the art using available methods. Thus, Applicants submit that those skilled in the art would understand the bounds of the claims when read in light of the specification and Claims 1, 7, and 19 are

definite and patentable. Applicant requests that these claims and their dependent Claims 2-6, 8-12 and 19-22 be allowed.

Applicants note that the Decision on Appeal also indicated that the effect of Aspergum on patentability should be considered. The Board took judicial notice of the fact that aspirin is available in three dosage forms: 81, 325 and 500 mg/tablet which would correspond to dosages of 162, 650 and 1000 mg after two tablets are consumed. The directions for use of Aspergum (included in the attachment at Exhibit A) indicates that two tablets should be chewed, each tablet having 227 mg of aspirin. The minimum dose of Aspergum is 227 mg (454 mg at recommended dose). This dose is substantially higher than a typical minimum dose of aspirin of 81 mg (162 mg at recommended dose). Therefore, Applicant submits that Aspergum does not include less than a typical amount of medicament to achieve a bioequivalent effect as required by the present invention and therefore would not anticipate or make the present invention, as presently claimed, obvious.

In light of the foregoing comments, the Applicants respectfully submit that the application is in condition for allowance and request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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EXHIBIT A

(Aspergum Aspirin Pain Reliever Web Page)

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Indications:

For the temporary relief of minor aches and pains associated with headache, common cold and reduces fever.

Directions:

- **Adults and children 12 years of age and over:** Chew 2 tablets every 4 hours, not more than 16 tablets in 24 hours, or as directed by a doctor.
- **Children under 12 years of age:** Consult a doctor.

Store between 15°C - 25°C (59° - 77°F). Protect from excessive moisture.

Ingredients:

Active Ingredients: Per Tablet: Aspirin (227 mg (3.5 gr))

Inactive Ingredients: Acacia, Acesulfame K, Artificial Orange Flavor, Beeswax, Carnauba Wax, Corn Syrup, Gelatin, Gum Base, Lecithin, Opalux Orange Dye, Opacolor Pharmaceutical Glaze, Starch, Sugar, Sugar 6x, Talc, Titanium Dioxide

Warnings:

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported associated with aspirin.

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor should take aspirin or other pain relievers/fever reducers. Aspiring may cause stomach bleeding.

Allergy Alert: Do not use if allergic to salicylates (including aspirin).

Ask a doctor before use if you have:

- asthma
- ulcers
- bleeding problems
- stomach problems that persist or recur, such as heartburn, upset stomach or stomach pain
- has tonsillectomy or oral surgery in the past 7 days

Ask a doctor or pharmacist before if you are taking a prescription drug for anticoagulant (thin the blood), diabetes, gout or arthritis.

Stop use and ask a doctor if

- redness or swelling is present
 - new symptoms occur
 - pain worsens or lasts more than 10 days
 - fever worsens or lasts more than 3 days
 - sore throat is severe, lasts for more than 2 days, is accompanied or followed by flu-like symptoms, headache, rash, nausea, or vomiting
 - ringing in the ears or loss of hearing occurs
- These symptoms could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important to avoid use aspirin during the last 3 months of pregnancy, unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.

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